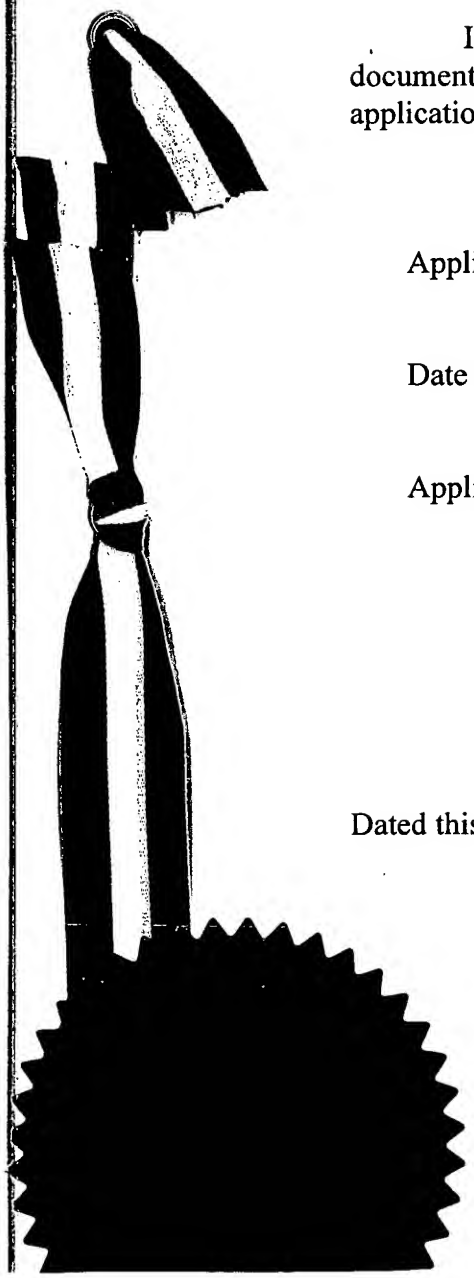

Patents Office
Government Buildings
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Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	PCT/IE03/00046
Date of Filing	25 March 2003
Applicant	AVE CONNAUGHT, an Irish company of Arthur Cox Building, Earlsfort Terrace, Dublin 2, and FRANK CLARKE, an Irish citizen of 44 Carrigmore, Lackagh, Turloughmor, County Galway.

Dated this 4 day of November 2005.

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PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/IE 03 / 00046

International Filing Date 25 MAR 2003

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* PN680PCT

Box No. I TITLE OF INVENTION

Improved Packaging for Stents and Stent Delivery Systems

Box No. II APPLICANT ☐ This person is also inventor

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

AVE Connaught
Arthur Cox Building
Earlsfort Terrace
Dublin 2

Telephone No.

Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State *(that is, country)* of nationality: IE

State *(that is, country)* of residence: IE

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

CLARKE, Frank
44 Carrigmore
Lackagh
Turloughmor
County Galway

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: IE

State *(that is, country)* of residence: IE

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

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Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country.)*

GATES, Marie Christina Esther; LANE, Cathal Michael;
WALSH, Michael Joseph; SHORTT, Peter Bernard;
PARKES, Andrew John Aykroyd; CURLEY, Donnacha;
MOORE, Barry;

TOMKINS & CO., 5 Dartmouth Road, Dublin 6, IE

Telephone No. +353 1 6605033

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Teleprinter No.

Agent's registration No. with the Office

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*	This person is:
FARRELL, Thomas 25 Sli an Bhradan Claregalway Co. Galway	☐ applicant only ☒ applicant and inventor ☐ inventor only *(If this check-box is marked, do not fill in below.)*
	Applicant's registration No. with the Office
State *(that is, country)* of nationality: IE	State *(that is, country)* of residence: IE

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	☐ applicant only ☐ applicant and inventor ☐ inventor only *(If this check-box is marked, do not fill in below.)*
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	☐ applicant only ☐ applicant and inventor ☐ inventor only *(If this check-box is marked, do not fill in below.)*
	Applicant's registration No. with the Office
State *(that is, country)* of nationality:	State *(that is, country)* of residence:

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	☐ applicant only ☐ applicant and inventor ☐ inventor only *(If this check-box is marked, do not fill in below.)*
	Applicant's registration No. with the Office
State *(that is, country)* of nationality:	State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

☐ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **MZ** Mozambique, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZM** Zambia, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

☐ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **BG** Bulgaria, **CH & LI** Switzerland and Liechtenstein, **CY** Cyprus, **CZ** Czech Republic, **DE** Germany, **DK** Denmark, **EE** Estonia, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, **SK** Slovakia, **TR** Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☐ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GQ** Equatorial Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

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☐ **AM** Armenia	☐ **ID** Indonesia	☐ **PL** Poland
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☐ **GH** Ghana	☐ **NO** Norway	

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ ..... ☐ ..... ☐ .....

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Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1)				
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

** Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / EP

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII DECLARATIONS

The following declarations are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*:		Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor :	
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent :	
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application :	
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America) :	
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty :	

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains**:

(a) the following number of **sheets in paper form**:

request (including declaration sheets)	:	5
description (excluding sequence listing part)	:	6
claims	:	2
abstract	:	1
drawings	:	3
Sub-total number of sheets	:	17
sequence listing part of description *(actual number of sheets if filed in paper form, whether or not also filed in computer readable form, see (b) below)*	:	
Total number of sheets	:	17

(b) sequence listing part of description filed in **computer readable form**

(i) ☐ only (under Section 801(a)(i))

(ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii))

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained *(additional copies to be indicated under item 9(ii), in right column)*: .....

This international application is **accompanied** by the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

	Number of items
1. ☒ fee calculation sheet	:
2. ☐ original separate power of attorney	:
3. ☐ original general power of attorney	:
4. ☐ copy of general power of attorney; reference number, if any:	:
5. ☐ statement explaining lack of signature	:
6. ☐ priority document(s) identified in Box No. VI as item(s):	:
7. ☐ translation of international application into *(language)*:	:
8. ☐ separate indications concerning deposited microorganism or other biological material	:
9. ☐ sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other))	
(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:
(ii) ☐ *(only where check-box (b)(i) or (b)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column	:
10. ☒ other *(specify)*: Letter	:

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

GATES, Marie Christina Esther

For receiving Office use only

1. Date of actual receipt of the purported international application: 25 MAR 2003

2. Drawings:
☒ received:
☐ not received:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority (if two or more are competent): ISA / EP

6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

Improved Packaging for Stents and Stent Delivery Systems

Field of the Invention

The present invention relates to a packaging system for drug-coated or treated stents and a method of packaging stents which minimise the level of exposure of the stents to oxygen, moisture and light and at the same time prevent oxygen and moisture scavenger packs touching the stent or delivery system.

Background to the Invention

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. A number of methods and devices for treating coronary heart disease have been developed, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

One method for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial expansion. This is generally accomplished by inflating a balloon within the narrowed lumen of the affected artery. The wall of the artery itself may also be stretched as the balloon is inflated. With simple angioplasty, the balloon is threaded through the artery with a catheter and inflated at the place where the blood vessel is blocked. After the procedure, the balloon is then removed. With simply angioplasty alone, arteries may close up again or re-narrow. This narrowing is known as restenosis.

To reduce the risk of restenosis, a stent may also be inserted during angioplasty. A stent is a tube, often made of metals or occasionally plastic materials that is inserted into a vessel or a passage in the body to keep the lumen of the vessel open and to prevent closure due to a stricture or external compression. The use of a stent may reduce the risk of restenosis. However, stent insertion can cause undesirable reactions such as inflammation, infection, thrombosis, or proliferation of cell growth that occludes the passageway.

Restenosis occurs because the blood vessel wall is injured when the stent is implanted. The area then becomes inflated and new cells form scar tissue. The arterial walls may become so thick in some instances that they sometimes protrude into the mesh of the stent. In such cases, a further angioplasty may be undergone, and a new stent may be placed inside the existing one. If restenosis continues, the eventual alternative may be bypass surgery.

Alternatively, a treated stent may be inserted during the angioplasty. Such a treated stent may eliminate the need for repeat angioplasties and could spare some patients the trauma, risk and prolonged recovery associated with heart bypass surgery. The treated stent contains a therapeutic agent to assist in preventing restenosis. The coatings are bioengeered to release doses of the therapeutic agent and may or may not be contained on a coating on the stent. Agents contemplated act to stop new cells from forming without impairing the healing of the vessel. Agents may also dampen inflammation and have antibiotic properties.

However, because the treated stent comprises a therapeutic drug, treated stents present problems associated with drug administration. For example, for a drug to be administered effectively, the integrity of the drug's effective dosage should be maintained. Certain drugs require regulated conditions for efficacy, such as regulated air circulation or lack thereof, regulated exposure to light and oxygen.

Prior art packaging systems for coated stents have typically comprised a thermoform tray insert in a foil pouch, or a thermoform tray having a Tyvek ™ lid in a foil pouch, into which the stent is vacuum packed. Such conventional packaging for stents do not provide for regulation of ambient conditions such as circulation of air or exposure to light and oxygen. Without such appropriate regulation, the efficacy of the drug and/or drug coating maybe reduced. Moreover, these packages tend to be heavier than those of the present invention, they utilise more material and they require more operator handling time to pack and so are more labour intensive to produce.

Object of the Invention

It is thus an object of the present invention to provide a package which optimises ambient conditions for treated stents. It is also an object to provide a package for treated stents and their associated delivery systems, which allows the inclusion of oxygen and moisture absorbing agents within the sealed package but which prevents the absorbing agents touching the stent or delivery system so that no residue can be left on the stent or delivery system. The package must also be suitable for sterilisation by conventional techniques such as ethylene oxide (EtO) and gamma irradiation.

Summary of the Invention

According to the present invention there is provided a package for a drug-coated stent comprising a tray adapted to receive a coiled stent delivery system and a pouch adapted to receive the tray and coiled stent delivery system, the tray containing at least one recess adapted to retain an oxygen or moisture scavenger pack.

The tray may be provided with channels into which the coils of the coiled stent delivery system can be located.

The package may further comprise a lid engagable with the tray and adapted to retain the scavenger pack in the recess in the tray and in communication with the internal environment of the pouch.

The tray may also comprise a pair of recesses adapted to retain a pair of scavenger packs. In particular the tray may comprise a pair of recesses adapted to retain oxygen and/or moisture scavenger packs, and the lid may comprise two apertures which overlie the recesses in the tray base when the lid and tray base are fitted together.

The lid and tray may be a snap fit together. The lid may be provided with a plurality of lugs which extend from the face of the lid which would overlie the tray base when the package is assembled, the tray base being provided with a plurality of cavities into which the lugs of the lid fit when the package is assembled.

Brief Description of the Drawings

The invention will now be described in greater detail with reference to the accompanying drawings in which:

Figure 1 shows a packaging system in accordance with the invention, with the treated stent and delivery system loaded on a tray base and the tray lid and absorber packs in exploded view,

Figure 2a shows a top plan view of the tray base in greater detail,

Figure 2b shows a front view of the tray base,

Figure 3a shows a top plan view of the tray lid in greater detail, and

Figure 3b shows a front view of the tray lid.

Detailed Description of the Drawings

As shown in Figure 1, the packaging system for a treated stent delivery system takes the form of a pouch or bag (1), a tray base (2) and a tray lid (3). The pouch (1) is formed from two layers of laminated foil (5) which are sealed together. A suitable foil is that available from Perfecseal Ltd. under the trade name 35781-G. The tray base and lid are produced by thermoforming **from** GPET co-polyester in a conventional manner. A suitable thickness for the tray base and lid is about 0.64 +/- 0.04mm.

The tray base (2) has a body portion (6) which is of generally semi-circular configuration with three arms (7) which extend outwardly from the outer circumferential edge (8) of the tray base (2). These arms (7) are formed with a series of channels or grooves (9) which extend along the arm (7) parallel to the circumference of the semi-circular body portion (6) and would be concentric with the tray base (2) if it were a complete circle. The channels (9) are thus curved in the plane of the tray base (2). The channels (9) are adapted to receive the coils of a coiled stent delivery system and are

provided at regular intervals along their course, with tabs (10) which serve to hols the delivery system within the channels (9).

The body portion (6) of the tray base (2) is also provided with two recesses (11) adapted to receive moisture and/or oxygen absorber or scavenger packs. Suitable oxygen and moisture absorber packs are commercially available from Mitsubishi Gas chemical company, Inc./(Pharmakeep KD-20™), and Silgel Ltd./(4g Molecular Sieve sachets), respectively.

The packaging system also comprises a tray lid (12) which is of generally semi-circular configuration and which is a snap fit with the tray base (2). The lid (12) has two apertures (13) which, when the lid (12) is fitted onto the tray base (2) overly the recesses (11) which hold the absorber packs. Thus when the stent and delivery system are packaged on the tray base (2) with the lid (12) in place, and placed in the pouch (1), the absorber packs are in contact with the internal pouch environment via the apertures (13) in the lid (12). The absorber packs are thus ideally placed to scavenge oxygen and moisture within the pouch, but cannot touch the stent or delivery system.

The tray lid (12) is provided with three lugs (14) on the surface of the lid (12) which abuts the tray base (2) when the lid and base are assembled together. These lugs (14) are engageable with three cavities (15) in the tray base (2) so that the lugs (14) and cavities (15) together provide a snap-fit mechanism for the lid and tray base.

The advantage of not putting the absorber packs into direct contact with the delivery system is that there is a possibility that tiny amounts of content residue would be present on the outside of each pack, and this residue would adversely interact with the drug or other coating on the stent.

Example 1

The process for packaging a stent comprises placing the drug-coated stent, mounted on a delivery system and loaded into a coiled dispenser onto the tray base so that the coils of the delivery system rest within the channels or grooves on the tray base. The scavenger packs are then placed within the recesses and the tray lid is snapped into

place. The delivery system mounted on the tray is then placed in the pouch, as shown in Figure 1.

In a single operation the open end of the pouch is flushed with nitrogen and vacuum-sealed, so that the two edges of the pouch are sealed together.

The inert gas used to flush the package is preferably nitrogen. The nitrogen is flushed for between 1 and 10 seconds at a pressure of 10 to 30psi.. The vacuum draw down time is suitably 1 second, up to 10 seconds. The package may be sealed by clamping the edges of the package between upper and lower jaws of a sealing device. The seal time may be from 1 to 10 seconds, with an upper jaw seal temperature of 110 to 200 °C and a lower jaw seal temperature of 60 to 100 ° C and the seal pressure may be from 30 to 100 psi.

The sealed pouch is then sterilised by gamma radiation in a conventional manner.

Example 2

The process for packaging a stent which is sterilised by ethylene oxide is slightly different. In this embodiment the Treated stent mounted on a delivery system and loaded onto a coiled dispenser, is placed in the tray, with the scavenger packs in place, and the lid is put in place. The tray is then placed in a pouch formed from one layer of a breathable membrane and one layer of a foil material. The breathable provides an entry and exit point for the ethylene oxide gas in the sterilisation process. The pouch containing the loaded tray is then sealed at its open end. The sealing temperature is 140-160°C, the pressure is 90-100psi and the dwell time is approximately 1-2 sec. The package is then sterilised using ethylene oxide in a conventional manner. After sterilisation the pouch is then vacuum-sealed within an outer all foil pouch following flushing with nitrogen.

The words "comprises/comprising" and the words "having/including" when used herein with reference to the present invention are used to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

Claims

1. A package for a drug-coated stent comprising a tray adapted to receive a coiled stent delivery system and a pouch adapted to receive the tray and coiled stent delivery system, the tray containing at least one recess adapted to retain an oxygen or moisture scavenger pack.

2. A package as claimed in claim 1 wherein the tray is provided with channels into which the coils of the coiled stent delivery system can be located.

3. A package as claimed in any preceding claim, further comprising a lid engagable with the tray and adapted to retain the scavenger pack in the recess in the tray and in communication with the internal environment of the pouch.

4. A package as claimed in any preceding claim comprising a pair of recesses adapted to retain a pair of scavenger packs.

5. A package as claimed in any preceding claim comprising a pair of recesses adapted to retain oxygen and/or moisture scavenger packs, the lid comprising two apertures which overlie the recesses in the tray base when the lid and tray base are fitted together.

6. A package as claimed in any preceding claim wherein the lid and tray are a snap fit.

7. A package as claimed in claim 6, wherein the lid is provided with a plurality of lugs which extend from the face of the lid which would overlie the tray base when the package is assembled, the tray base being provided with a plurality of cavities into which the lugs of the lid fit when the package is assembled.

8. A package as claimed in any preceding claim wherein the pouch is made of a plastics covered foil.

9. A kit of parts comprising a package as claimed in any preceding claim, a drug-coated stent, and at least one oxygen or moisture scavenger pack.

10. A method of packaging a drug-coated or treated stent and stent delivery system comprising :-

(a) placing a coiled stent delivery system onto a tray base adapted to receive it,

(b) placing a moisture and an oxygen scavenger pack within a recess formed in the tray base,

(c) placing a lid over the tray base, the lid having apertures which overly the recesses in the tray base when the lid and tray are assembled together,

(d) placing the assembled tray, lid and delivery system of step (c) into a plastics covered foil pouch,

(e) flushing the pouch with an inert gas,

(f) applying a vacuum to the pouch,

(g) sealing the open end of the pouch, and

(h) sterilising the package.

Abstract

A packaging system for drug coated or treated stents and their associated delivery systems is disclosed. The package minimises the level of exposure of the stent to oxygen, moisture and light using scavenger packs which are prevented from touching the stent or delivery system. The packaging system comprises a tray with a recess for holding a scavenger pack, the tray being adapted to also hold a coiled delivery system.

Fig. 1

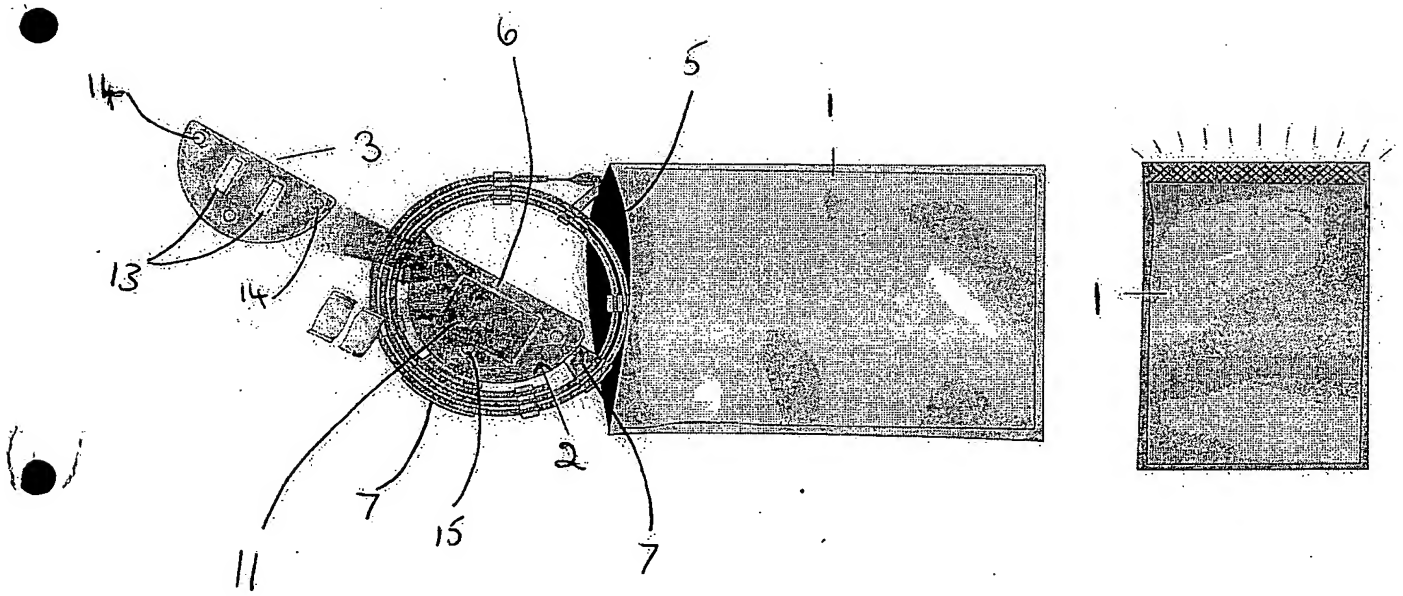

Figure 1

Figure 2a

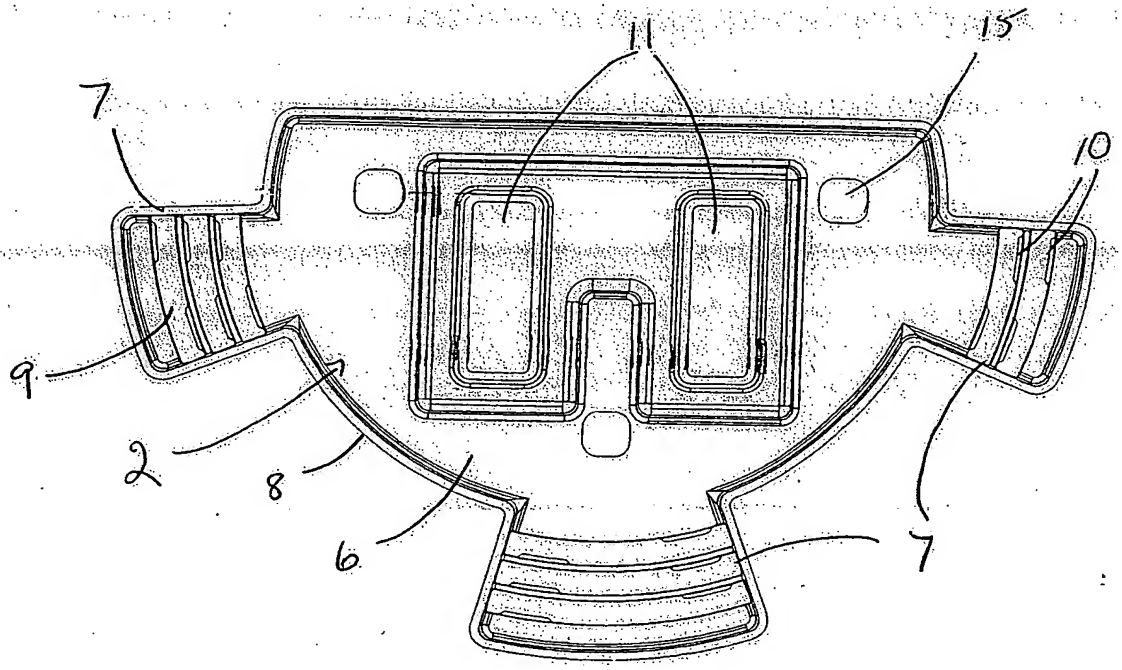

Figure 2b

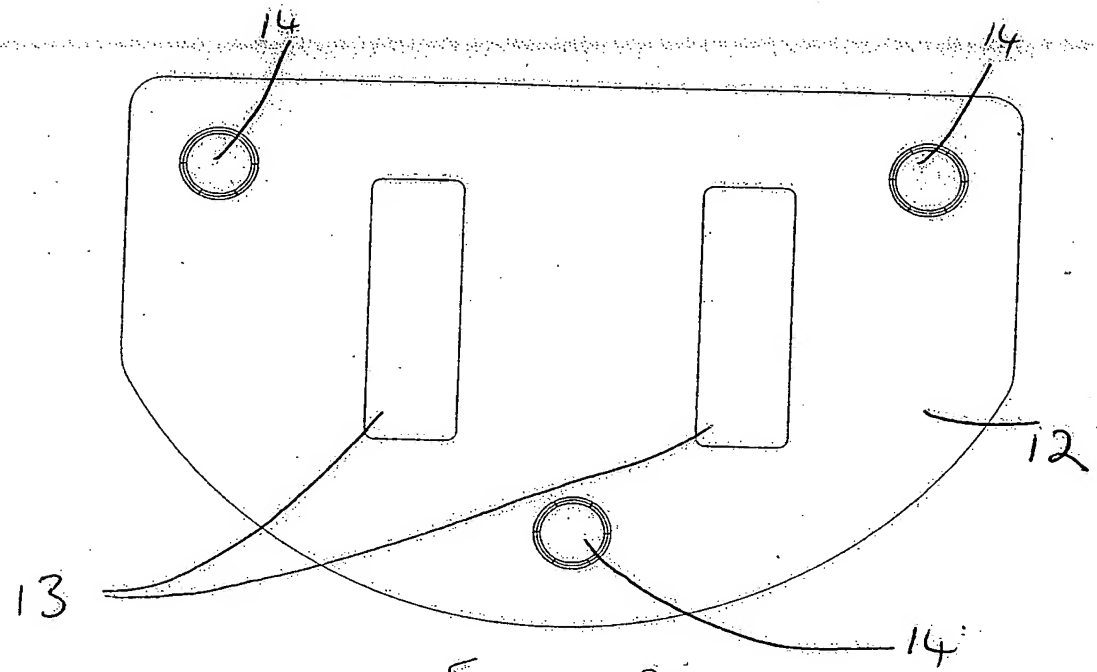

Figure 3a

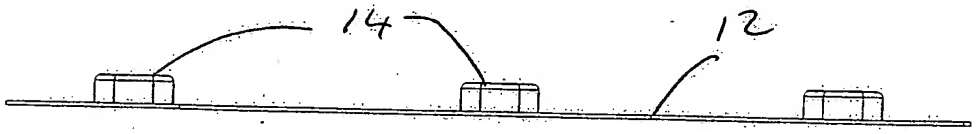

Figure 3b

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